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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS VACCINES AND DIAGNOSTICS, INC. AND NOVARTIS PHARMA AG, Plaintiffs, v. PFIZER, INC., Defendant.	Civil Action No. _____ ***Document electronically filed***

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs Novartis Vaccines and Diagnostics, Inc. ("NVD") and Novartis Pharma AG ("Novartis Pharma") (collectively, "Novartis") by their attorneys, for their Complaint, allege as follows:

1. Plaintiff NVD is a corporation organized and existing under the laws of the state of Delaware, having its corporate offices and principal place of business at 350 Massachusetts Avenue, Cambridge, Massachusetts. Plaintiff Novartis Pharma is a foreign corporation existing under the laws of Switzerland with its principal place of business at Lichtstrasse 35, Basel, Switzerland CH-4056. Defendant Pfizer, Inc. ("Pfizer") is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 235 East 42nd

Street, New York, New York.

2. This is an action arising under the patent laws of the United States, codified at 35 U.S.C. §§ 1, et seq., over which this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), for infringement of U.S. Patent Nos. 7,576,176 ("the '176 patent"), 8,524,251 ("the '251 patent"), 8,394,390 ("the '390 patent"), 8,398,988 ("the '988 patent"), 8,840,907 ("the '907 patent"), and 8,834,888 ("the '888 patent") (collectively, the "Novartis Patents"). The action arises out of the preparation, manufacture, importation, offer for sale, and sale by Pfizer of a meningococcus B vaccine, bivalent rLP2086 ("Bivalent rLP2086"), in violation of the claims of the Novartis Patents. Bivalent rLP2086 has recently been approved by the U.S. Food and Drug Administration ("FDA") under the trade name Trumenba®.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Pfizer is subject to personal jurisdiction in New Jersey because, among other things, it maintains operations in New Jersey, and Pfizer is in the business of marketing pharmaceutical products, which it distributes and sells throughout the U.S., including in New Jersey. Upon information and belief, Pfizer has committed and continues to commit acts of patent infringement in New Jersey, and has harmed and continues to harm Novartis by offering to sell or selling infringing products in New Jersey.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

A. PIONEERING INVENTIONS OF DR. RAPPOULI AND COLLEAGUES

6. This dispute involves infringement by Pfizer of six U.S. patents assigned to Novartis Pharma and exclusively licensed to NVD for, *inter alia*, the importation, use, offering for sale, and sale of vaccine products in the U.S. The patents at issue describe and claim the pioneering inventions of a Novartis scientist, Dr. Rino Rappouli, and his colleagues, relating to a *Neisseria meningitidis* serogroup B ("MenB") vaccine.

7. Prior to the groundbreaking inventions of Dr. Rappouli and his colleagues, there was a longstanding, unmet need for a vaccine that would provide broad-based protective immunity against MenB. *N. meningitidis* can cause serious, life-threatening meningitis and septicemia, especially in the young. Strains of this bacterium are divided into "serogroups" based on their capsular polysaccharides, and the "B" serogroup is one of the leading causes of bacterial meningitis in the developed world, including the U.S. Capsular polysaccharides have often been used in vaccine development, and have been shown to provide protective immunity for other *N. meningitidis* serogroups. MenB presented a problem, however, because its capsular polysaccharide is the same as a carbohydrate component of certain human glycoproteins, causing the immune system to identify them as self antigens. Alternative vaccine research focused on surface-exposed proteins contained in MenB outer membrane vesicles, but vaccine candidates developed from this research provided poor protective immunity across different strains of MenB.

8. In 1996, Dr. Rappouli began work on a new approach for developing vaccines. This approach, which he coined as "reverse vaccinology," has been described as revolutionary. It permits characterization of antigens independent of their abundance and immunogenicity

during infection, without the need to grow the pathogen itself. Dr. Rappouli predicted that, using his approach, many vaccines not previously possible to develop would become a reality.

9. Dr. Rappouli and his colleagues designed and implemented a plan to use reverse vaccinology to identify vaccine candidates for MenB. Their work ultimately resulted in the development of Novartis' Bexsero®, which was the first vaccine shown to provide protective immunity against a broad range of MenB strains. Bexsero is approved in more than thirty countries, including Canada, Australia, the U.S., and numerous other countries across the European Union. Since the launch of Bexsero in 2013, over half a million doses have been distributed worldwide. In 2014, Novartis provided nearly 30,000 doses of Bexsero to students and staff at Princeton University and the University of California, Santa Barbara following MenB outbreaks on their campuses under an investigational new drug designation from the FDA. Further, the U.S. Centers for Disease Control and Prevention have recommended that the incoming freshman class at Princeton University in the at-risk group receive Bexsero.

10. On or about April 7, 2014, the FDA granted Bexsero a Breakthrough Therapy designation, intended to expedite the development and review of new medicines that treat serious or life-threatening conditions. On or about July 24, 2014, Novartis submitted a Biological License Application ("BLA") to the FDA for marketing approval for Bexsero in the U.S. On January 23, 2015, the FDA announced that it had approved Bexsero for marketing and sale to prevent invasive meningococcal disease caused by MenB in individuals 10 through 25 years of age. GlaxoSmithKline has announced that it will acquire Novartis' global vaccines business, which would include the Novartis Patents and the intellectual property rights to Bexsero.

B. ASSERTED PATENTS

11. Dr. Rappouli's and his colleagues' inventions are described and claimed in six U.S. patents assigned to Novartis Pharma and at issue in this case:

12. The '176 patent, issued on August 18, 2009, is entitled "*Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '176 patent is attached as Exhibit 1.

13. The '251 patent, issued on September 3, 2013, is entitled "*Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '251 patent is attached as Exhibit 2.

14. The '390 patent, issued on March 12, 2013, is entitled "Neisserial Antigenic Peptides," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '390 patent is attached as Exhibit 3.

15. The '988 patent, issued on March 19, 2013, is entitled "Adjuvanting Meningococcal Factor H Binding Protein," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '988 patent is attached as Exhibit 4.

16. The '907 patent, issued on September 23, 2014, is entitled "Isolated Protein and Compositions Comprising the Protein," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '907 patent is attached as Exhibit 5.

17. The '888 patent, issued on September 16, 2014, is entitled "Adjuvanting Meningococcal Factor H Binding Protein," and is solely assigned to Novartis Pharma and exclusively licensed to NVD. A true and correct copy of the '888 patent is attached as Exhibit 6.

C. PFIZER'S INFRINGING VACCINE

18. Pfizer's Bivalent rLP2086 vaccine practices the inventions claimed in the '176, '251, '390, '988, '907, and '888 patents.

19. On or before June 14, 2014, Pfizer submitted to the FDA a BLA for Bivalent rLP2086. On October 29, 2014, the FDA announced the approval of Bivalent rLP2086, under its trade name Trumenba, which the FDA states is "licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age." The FDA reports that "Trumenba is manufactured by Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc., Philadelphia, Pennsylvania." The approved packaging description of the product states:

> Trumenba is a sterile suspension composed of two recombinant lipidated factor H binding protein (fHBP) variants from *N. meningitidis* serogroup B, one from fHBP subfamily A and one from subfamily B (A05 and B01, respectively). The proteins are individually produced in *E. coli*. Production strains are grown in defined fermentation growth media to a specific density. The recombinant proteins are extracted from the production strains and purified through a series of column chromatography steps. Polysorbate 80 (PS80) is added to the drug substances and is present in the final drug product.
>
> Each 0.5 mL dose contains 60 micrograms of each fHBP variant (total of 120 micrograms of protein), 0.018 mg of PS80 and 0.25 mg of Al^{3+} as AlPO4 in 10 mM histidine buffered saline at pH 6.0.

20. On November 18, 2014, Pfizer began offering Trumenba for sale to healthcare providers, retail pharmacies, hospitals, and college health centers in the U.S. that will stock and administer the vaccine. This manufacture, use, offer for sale, sale, or importation of Bivalent rLP2086 infringes claims of the '176, '251, '390, '988, '907, and '888 patents.

D. PFIZER'S KNOWLEDGE OF THE PATENTS-IN-SUIT

21. Upon information and belief, Pfizer had pre-suit knowledge of the '176, '251, '390, '988, '907, and '888 patents.

22. The '176 patent was cited by the U.S. Patent & Trademark Office and two different patent prosecutors working on behalf of Pfizer during the prosecution of U.S. Patent Nos. 8,101,194 ("the '194 patent"), 8,563,006 ("the '006 patent"), 8,563,007 ("the '007 patent"), and 8,574,597 ("the '597 patent"), which are owned by subsidiaries of Pfizer. These citations occurred on January 6, 2011, April 9, 2012, July 1, 2013, and August 28, 2012, respectively.

23. The WIPO publication (WO 03/20756) of the '907 patent's priority PCT application was cited by Pfizer patent prosecutors during the prosecution of the '194, '006, '007, and '597 patents on May 9, 2005, April 9, 2012, July 1, 2013, and October 3, 2012, respectively.

24. The WIPO publication (WO 01/31019) of the '390 patent's priority PCT application was also cited by a Pfizer patent prosecutor during the prosecution of the '006, '007, and '597 patents. These citations occurred on September 27, 2012, July 1, 2013, and October 3, 2012, respectively.

25. The WIPO publication (WO 99/57280) of the '251 patent's priority PCT application was cited by a Pfizer patent prosecutor during the prosecution of the '006, '007, and '597 patents on April 9, 2012, July 1, 2013, and January 7, 2009, respectively.

26. The '988 patent, which is the parent of the '888 patent, was also cited by a Pfizer patent prosecutor during the prosecution of the '006 patent, on September 4, 2013, and the '007 patent, on July 15, 2013.

27. Upon information and belief, at the time Pfizer cited these patents and patent publications, Pfizer knew or should have known it was developing a vaccine that infringed the Novartis Patents. The applications for the Pfizer '194, '006, '007, and '597 patents contain

claims relating to factor H Binding Protein-based meningococcal vaccines, as do the Novartis Patents.

28. Additionally, upon information and belief, because both Pfizer and Novartis have submitted BLAs to the FDA for vaccines to treat MenB, Pfizer closely tracks the status of Novartis' patents and patent applications relating to MenB, including the Novartis Patents, and either knew or should have known that its actions would constitute infringement of the Novartis Patents.

COUNT I — INFRINGEMENT OF THE '176 PATENT UNDER 35 U.S.C. § 271

29. Novartis incorporates each of the preceding paragraphs 1-28 as if fully set forth herein.

30. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the '176 patent.

31. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the '176 patent.

32. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer's Bivalent rLP2086 vaccine.

33. Pfizer has committed and will commit these acts of infringement without license or authorization.

34. Unless Pfizer is enjoined from infringing the '176 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

35. Upon information and belief, Pfizer knew of the ’176 patent prior to the filing of this Complaint.

36. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the ’176 patent.

37. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer’s infringement is willful.

38. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the ’176 patent in disregard of Novartis’ rights, making this case exceptional and entitling Novartis to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT II — INFRINGEMENT OF THE ’251 PATENT UNDER 35 U.S.C. § 271

39. Novartis incorporates each of the preceding paragraphs 1-38 as if fully set forth herein.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer’s Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the ’251 patent.

41. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer’s Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the ’251 patent.

42. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer’s Bivalent rLP2086 vaccine.

43. Pfizer has committed and will commit these acts of infringement without license or authorization.

44. Unless Pfizer is enjoined from infringing the ’251 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

45. Upon information and belief, Pfizer knew of the ’251 patent prior to the filing of this Complaint.

46. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the ’251 patent.

47. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer’s infringement is willful.

48. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the ’251 patent in disregard of Novartis’ rights, making this case exceptional and entitling Novartis to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT III — INFRINGEMENT OF THE ’390 PATENT UNDER 35 U.S.C. § 271

49. Novartis incorporates each of the preceding paragraphs 1-48 as if fully set forth herein.

50. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer’s Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the ’390 patent.

51. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the '390 patent.

52. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer's Bivalent rLP2086 vaccine.

53. Pfizer has committed and will commit these acts of infringement without license or authorization.

54. Unless Pfizer is enjoined from infringing the '390 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

55. Upon information and belief, Pfizer knew of the '390 patent prior to the filing of this Complaint.

56. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the '390 patent.

57. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer's infringement is willful.

58. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the '390 patent in disregard of Novartis' rights, making this case exceptional and entitling Novartis to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV — INFRINGEMENT OF THE '988 PATENT UNDER 35 U.S.C. § 271

59. Novartis incorporates each of the preceding paragraphs 1-58 as if fully set forth herein.

60. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the '988 patent.

61. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the '988 patent.

62. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer's Bivalent rLP2086 vaccine.

63. Pfizer has committed and will commit these acts of infringement without license or authorization.

64. Unless Pfizer is enjoined from infringing the '988 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

65. Upon information and belief, Pfizer knew of the '988 patent prior to the filing of this Complaint.

66. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the '988 patent.

67. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer's infringement is willful.

68. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the ’988 patent in disregard of Novartis’ rights, making this case exceptional and entitling Novartis to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT V — INFRINGEMENT OF THE ’907 PATENT UNDER 35 U.S.C. § 271

69. Novartis incorporates each of the preceding paragraphs 1-68 as if fully set forth herein.

70. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer’s Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the ’907 patent.

71. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer’s Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the ’907 patent.

72. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer’s Bivalent rLP2086 vaccine.

73. Pfizer has committed and will commit these acts of infringement without license or authorization.

74. Unless Pfizer is enjoined from infringing the ’907 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

75. Upon information and belief, Pfizer knew of the ’907 patent prior to the filing of this Complaint.

76. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the '907 patent.

77. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer's infringement is willful.

78. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the '907 patent in disregard of Novartis' rights, making this case exceptional and entitling Novartis to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VI — INFRINGEMENT OF THE '888 PATENT UNDER 35 U.S.C. § 271

79. Novartis incorporates each of the preceding paragraphs 1-78 as if fully set forth herein.

80. The commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine does and will constitute an act of infringement of one or more claims of the '888 patent.

81. Upon information and belief, Pfizer does and will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pfizer's Bivalent rLP2086 vaccine. The foregoing actions by Pfizer constitute infringement of the '888 patent.

82. Upon information and belief, Pfizer has made, and will continue to make, substantial preparations in the U.S. to manufacture, sell, offer to sell, and/or import Pfizer's Bivalent rLP2086 vaccine.

83. Pfizer has committed and will commit these acts of infringement without license or authorization.

84. Unless Pfizer is enjoined from infringing the '888 patent, Novartis will suffer irreparable injury for which damages are an inadequate remedy.

85. Upon information and belief, Pfizer knew of the '888 patent prior to the filing of this Complaint.

86. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Bivalent rLP2086 does and will constitute an unjustifiably high risk of infringement of the '888 patent.

87. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Bivalent rLP2086. Thus, Pfizer's infringement is willful.

88. Upon information and belief, Pfizer continues to willfully, wantonly, and deliberately infringe the '888 patent in disregard of Novartis' rights, making this case exceptional and entitling Novartis to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests the following relief:

(a) Judgment that Pfizer's Bivalent rLP2086 infringes one or more claims of the '176, '251, '390, '988, '907, and '888 patents;

(b) Preliminary and permanent injunctions enjoining Pfizer, and all persons acting in concert with Pfizer, from making, using, selling, offering for sale, or importing Pfizer's Bivalent rLP2086, or any other product the making, using, selling, offering for sale, or importing of which infringes one or more claims of the '176, '251, '390, '988, '907, and '888 patents;

(c) Judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(d) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(e) An award of Novartis' costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiffs demand a jury trial as to all matters triable of right by a jury.

Respectfully submitted,

MORRISON & FOERSTER LLP

Dated: February 18, 2015

/s/ David J. Fioccola

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